K111808
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11.3 510(K) SUMMARY

AUG - 1 2011

Sponsor/manufacturing Information

Sponsor's name:	EDAP TMS France
Contact person:	Mr Bruno PAGES, Quality & Regulatory Affairs Director
Address of sponsor:	Parc d'activité la Poudrette 4 rue du Dauphiné 69120 Vaulx-en-Velin France
Telephone number :	(011) 33 4 72 15 31 50
Facsimile number :	(011) 33 4 72 15 31 51
Manufacturer name:	EDAP TMS France
Contact person:	Mr Bruno PAGES, Quality & Regulatory Affairs Director
Address of manufacturer:	Parc d'activité la Poudrette 4, rue du Dauphiné 69120 Vaulx-en-Velin France
Telephone number :	(011) 33 4 72 15 31 50
Facsimile number :	(011) 33 4 72 15 31 51

a) Proposed Device

Common name of the Medical Device	Extracorporeal Shock Wave Lithotripter and Accessories
Trade / Proprietary Name	SONOLITH® i-move Module
CFR Number	21 CFR 876.5990 (Extracorporeal shock wave lithotripter)
Regulatory Class	Class II (Special Controls)
Product Code	78 LNS
Common name of the Medical Device	Endo-Urology Table and Accessories
Trade / Proprietary Name	SONOLITH® Tables : TEU and ESWL_L8
CFR Number	21 CFR 876.4890 (Urological table and accessories)
Regulatory Class	Class II (Special Controls)
Product Code	MMZ

b) Predicate Device(s)

Device # 1 - EDAP TECHNOMED Inc. **Sonolith® Praktis**. K003529.
Device # 2 - EDAP TMS France SA. **Sonolith® I-sys treatment module and Sonolith® I-sys table.** K083614.
Device # 3 - EDAP International Corp. **EDAP LT.02 Shock Wave Lithotripter.** P880042.
Device # 4 - FMD, LLC.**Twinheads® TH-101 ESWL.** K030346

c) Device Description

The SONOLITH® i-move medical device is a lithotripter of ESWL type (Extracorporeal Shock Wave Lithotripsy). The physical principle consists in delivering pulsed pressure waves which are focalized on the stone to be treated, at fixed frequency or patient synchronized frequency.

The SONOLITH® i-move ESWL generator Diatron V uses a patented electrode including a reservoir with a highly conductive solution. This electrode type is the same for the previous generator Diatron IV and III used in clinics and hospitals for several years.

A membrane mounted on the top of the generator ensures the acoustical coupling between the generator and the patient's skin. Moreover, the generator benefits from a real time pressure servo control device.

The shock wave generation consists of emitting an electrical discharge at the first focus (F1) of the truncated ellipsoid. The shock wave generated is bent back by the ellipsoid's inner wall to be precisely concentrated at the second focus (F2). The highly conductive liquid incorporated into the electrode guarantees a very high stability of the electrical arc at F1 ensuring very low dispersion at F2.

The SONOLITH® i-move has to be coupled with, at least, one table dedicated at minimum, ESWL application, and one imaging system (Ultrasound scanner and/or X-ray C-arm). The two tables (TEU and ESWL_L8) are presented in the part hereafter (e: Intended Use).

d) Intended Use

The Sonolith® i-move is intended to fragment stones in the kidney (renal pelvis and renal calyces) and the ureter (upper, middle and lower ureter).

The ESWL_L8 table is intended for extracorporeal shock wave lithotripsy (ESWL) procedures in conjunction with the diagnostic and therapeutic module of the platform.

The TEU table is intended for urological diagnostics, endourological procedures and extracorporeal shock wave lithotripsy (ESWL) procedures in conjunction with the diagnostic and therapeutic module of the platform.

e) Summary of Studies

In accordance with FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters indicated for the Fragmentation of Kidney and Ureteral Calculi (August 9, 2000), EDAP TMS France conducted the following types of performance testing:

Test	Relevant standards or Guidance	Conclusions
Electrical safety testing	IEC 60601-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety" IEC 60601-1-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems" IEC 60601-2-36, "Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy"	The certified laboratory has concluded that the device in its full configuration is in compliance with the standards.
Electromagnetic compatibility testing	IEC 60601-1-2, "Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility"	The certified laboratory has concluded that the device in its full configuration is in compliance with the standard.
Shock Wave characterization measurements	IEC 61846, (1998), "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields"	The results, in reference to the details of the measurements and calculations, given in relevant part of 510(k) application, are found similar to the predicate devices characteristics.
X-ray and ultrasound localization accuracy testing	Section 8.B of the FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters indicated for the Fragmentation of Kidney and Ureteral Calculi (August 9, 2000)	The tests performed with the Sonolith i-move has resulted in localization accuracy of +/- 2 mm for both X-ray and Ultrasound systems.

Test	Relevant standards or Guidance	Conclusions
Road testing	Section 8.C of the FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters indicated for the Fragmentation of Kidney and Ureteral Calculi (August 9, 2000)	The test was performed on a mobile/transportable version of the treatment module associated with a patient support, an X-ray C-arm system and external Ultrasound System. The test showed no significant differences in performance specifications before and after road test.
Confirmatory clinical testing	primary objective of the Section 8.D of the FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters indicated for the Fragmentation of Kidney and Ureteral Calculi (August 9, 2000)	The confirmatory clinical study (2 clinical sites, 24 patients) established the labeling adequacy, the device functioning and the system ergonomics as well as the effectiveness and safety of the Sonolith i-move in patients with urinary stones.

f) Conclusion

The SONOLITH® i-move Module and the Tables (ESWL_L8 and TEU) are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG - 1 2011

EDAP TMS France
% Mr. Howard M. Holstein
Consultant
Hogan Lovells US LLP
Columbia Square – 555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K111808
Trade/Device Name: SONOLITH® i-move module
and SONOLITH® TABLES : ESWL L8 and TEU
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS, MMZ
Dated: June 24, 2011
Received: June 27, 2011

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known) : K111808

Device Name : **SONOLITH® i-move module and SONOLITH® TABLES : ESWL L8 and TEU**

Indications for Use :

The Sonolith® i-move is intended to fragment stones in the kidney (renal pelvis and renal calyces) and the ureter (upper, middle and lower ureter).

The ESWL_L8 table is intended for extracorporeal shock wave lithotripsy (ESWL) procedures in conjunction with the diagnostic and therapeutic module of the platform.

The TEU table is intended for urological diagnostics, endourological procedures and extracorporeal shock wave lithotripsy (ESWL) procedures in conjunction with the diagnostic and therapeutic module of the platform.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 111808